FUJIFILM

FUJIFILM Medical Systems U.S.A., Inc.
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510(k) Summary

DEC 1 3 2012

Date: November 1, 2012

K Number: K122535

Submitter's Information:

FUJIFILM Medical Systems U.S.A., Inc.
10 High Point Drive
Wayne, NJ 07470 USA
FDA Establishment Registration Number: 2431293

Contact Person:

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Identification of the Proposed Device:

Proprietary/Trade Name: Fujinon/Fujifilm EB-530 Series Bronchoscopes
Common Name: Bronchoscopes
Device Class: Class 2
Review Panel: Ear Nose & Throat
Classification Information:

Classification Name	CFR Section	Product Codes
Bronchoscope (flexible or rigid) and accessories	21 CFR 874.4680	EOQ

I. INDICATIONS FOR USE

The Fujinon/Fujifilm EB-530 Series Bronchoscopes are intended for the observation, diagnosis, and endoscopic treatment of the trachea and bronchial tree.

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II. DEVICE DESCRIPTION

Fujinon/Fujifilm EB-530 Series Bronchoscopes are intended for the observation, diagnosis and endoscopic treatment of the trachea and bronchial tree. The Fujinon/Fujifilm EB-530 Series Bronchoscopes are used in combination with the Fujinon/Fujifilm's video endoscope processors, light source, monitor, cart, foot switch, endoscopic accessories, other peripheral devices (e.g. printer, keyboard, etc.), and the legally marketed electrosurgical instruments.

There are three models included in this submission:

- EB-530S – Standard Type
- EB-530T – Treatment Type (includes 2.8mm forceps channel)
- EB-530H – Super Image Type (High resolution)

III. SUMMARY OF STUDIES

The subject device has been subjected to and passed electrical safety and EMC test requirements.

Fujinon/Fujifilm EB-530 Series Bronchoscopes were evaluated in accordance with the following safety and performance requirements in addition the applicable quality regulations:

IEC 60601-1	Medical electrical equipment - Part 1: General requirements for safety
IEC60601-1-1	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
IEC60601-1-2	Medical electrical equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and tests
IEC60601-2-18	Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment
ISO10993-1	Biological evaluation of medical devices

New pre-sterilized suction button SB-602 conforms to the applicable internal and international ISO testing requirements for Sterility.

The reprocessing instructions were updated and validated. No clinical testing was conducted.

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IV. SUBSTANTIAL EQUIVALENCE

Fujinon/Fujifilm EB-530 Series Bronchoscopes are substantially equivalent to the following device:

Legally Marketed Device(s)	510(k) #
Fujinon G5 Bronchoscopes	K050907

Comparison is outlined in the table below.

	Legally marketed Fujinon G5 Bronchoscope EB-470S (K050907)	**Proposed Device Model EB-530S**	**Proposed Device Model EB-530T**	**Proposed Device Model EB-530H**
Viewing direction	Forward/0degree	Forward/0degree	Forward/0degree	Forward/0degree
Observation range	3-100mm	3-100mm	3-100mm	3-100mm
Field of view	120 degrees	120 degrees	120 degrees	140 degrees
Distal end diameter	4.9mm	4.9mm	5.8mm	5.4mm
Flexible portion diameter	4.9mm	4.9mm	5.9mm	4.9mm
Bending capability	Up: 180 degrees	Up: 180 degrees	Up: 180 degrees	Up: 180 degrees
	Down: 130 degrees	Down: 130 degrees	Down: 130 degrees	Down: 130 degrees
Forceps channel diameter	2.0mm	2.0mm	2.8mm	2.0mm
Working length	600 mm	600 mm	600 mm	600 mm
Total length	870mm	870mm	870mm	870mm

All patient contact materials used in the proposed EB-530 Series Bronchoscopes remain the same as the legally marketed device.

V. CONCLUSION

Fujinon/Fujifilm EB-530 Series Bronchoscopes are substantially equivalent to the legally marketed device and conform to applicable medical device safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 13, 2012

FUJIFILM Medical Systems U.S.A., Inc.
% Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K122535
Trade/Device Name: Fujinon/Fujifilm EB-530 Series Bronchoscopes (EB-530S, EB-530T and EB-530H)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: November 1, 2012
Received: November 2, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K122535

Indications for Use

510(k) Number (if known): K122535

Device Name: Fujinon/Fujifilm EB-530 Series Bronchoscopes (EB-530S, EB-530T AND EB-530H)

Indications for Use: This device is intended for the observation, diagnosis, and endoscopic treatment of the trachea and bronchial tree.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number _____

Prescription Use X
(Per 21 CFR 801.109)